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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,429	12/03/2001	Akikuni Yagita	Q67403	6046

7590 10/22/2003

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EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 10/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/998,429

Applicant(s)

YAGITA, AKIKUNI

Examiner

Francisco C Prats

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

The response filed August 28, 2003, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

The terminal disclaimer filed on August 28, 2003, disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Pat. No. 6,403,083 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claims 18-20 are pending and are examined on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Ghoneum et al (Int. J. Immunotherapy 11(1):23-28 (1995)) (Ghoneum I) or Ghoneum (Natural Immunity 13(4):228 (1994)) (Ghoneum II).

Each of the cited references discloses administering the

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claimed therapeutic agent, AHCC, at a dosage rate of three grams per day, the exact dosage used by applicant to induce IL-12.

Because the prior art discloses administering the same ingredient in the same amount as recited in the claims, a holding of anticipation is clearly required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made..

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ghoneum et al (Int. J. Immunotherapy 11(1):23-28 (1995)) (Ghoneum I) or Ghoneum (Natural Immunity 13(4):228 (1994)) (Ghoneum II) in view of Fujii et al (U.S. Pat. 4,207,312).

As discussed above, the Ghoneum references disclose the administration of the claimed AHCC agent to cancer patients in the claimed amounts, thereby inducing IL-12. The Ghoneum references differ from the claims in that they do not administer

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additional components of fungal mycelia to the cancer patients. However, the artisan of ordinary skill at the time of applicant's invention clearly would have recognized that various extracts of fungal mycelia, such as those disclosed by Fujii were known to have anticancer activity. Thus, the artisan of ordinary skill at the time of applicant's invention clearly would have been motivated to have combined the cancer therapies of Ghoneum with the therapy of Fujii to have afforded the individual advantages of each of the known prior art methods.

It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ghoneum et al (Int. J. Immunotherapy 11(1):23-28 (1995)) (Ghoneum I) or Ghoneum (Natural Immunity 13(4):228 (1994)) (Ghoneum II) in view of Fujii et al (U.S. Pat.

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4,207,312), and in further view of Sugawara et al (U.S. Pat. 4,242,326).

Fujii and the Ghoneum references differ from the claims in not disclosing the use of hemolytic streptococci in combination with the AHCC. However, Sugawara discloses that components of hemolytic streptococci are useful as anti-cancer agents. Thus, the artisan of ordinary skill at the time of applicant's invention would have reasonably expected that components of hemolytic streptococci would be useful in anti-cancer compositions, including those containing the AHCC of Kosuna and the Ghoneum patents. Thus, the artisan of ordinary skill clearly would have been motivated to have combined the AHCC of Ghoneum and the fungal mycelia components of Fujii with the hemolytic streptococci components of Sugawara. As discussed above, it is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

It is therefore respectfully submitted that a holding of obviousness is clearly required.

Response to Arguments

All of applicant's argument has been fully considered but is not persuasive of error. Applicant asserts that the anticipation rejections are improper because applicant's own data demonstrates that administration of the claimed agent does not always result in induction of IL-12. Applicant's assessment of the data is incorrect. The specification states "[u]ntil **three months**, tumor regression was not found and the IL-12 level was not elevated." (Emphasis added.) Specification at page 17. Ultimately, administration of AHCC resulted in IL-12 levels of 240 ng/ml and 340 ng/ml. See Table 3. Moreover, applicant's argument is in direct contradiction to applicants own data presented in Examples 1 and 2, where AHCC administered by itself clearly induced IL-12. Further still, the only instances where AHCC was demonstrated to not induce IL-12, at least for awhile, was where shark cartilage was co-administered. See specification, Examples 7 and 8. Ghoneum did not administer shark cartilage along with the AHCC. Therefore, the data presented in Examples 7 and 8 is not directly comparable to the Ghoneum references. Lastly, it is clearly improper for

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applicant to base their entire disclosure on the IL-12-inducing properties of AHCC, then assert that it might not work, when faced with prior art demonstrating its prior use in the same manner, using the same dosage. On the current record, based on the fact that the same ingredient was administered to the same patient at the same dosage, IL-12 induction must have occurred. If applicant alleges that the prior art administration of AHCC did not result in IL-12 induction, applicant must prove it by clear and convincing evidence.

With respect to the issue of obviousness, it is noted initially, as argued by applicant, that the Ghoneum references do not refer to inducing IL-12 whereas the claims recite inducing IL-12 in a patient. However, by properly referring to the specification to determine those patients suited for the claimed process, it is clear that the claimed therapeutic method is intended for cancer patients. Specification, page 6, lines 12-14. Moreover, the additional fact that PSK, i.e. fungal mycelia components, do not necessarily induce IL-12 production does not render claim 19 non-obvious. Claim 19 requires co-administration of two ingredients, AHCC and PSK, that is all. Similarly, claim 20 requires only the administration of three ingredients, AHCC, fungal mycelia components and hemolytic streptococcus components. Clearly, the cited references

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disclose that all of the claimed ingredients are suitably administered for a common purpose -- the treatment of cancer. Coincidentally, cancer patients are exactly those disclosed in applicant's specification as being suitable recipients for the claimed therapeutic method. Specification, page 6, lines 12-14. Because the prior art suggests administering the claimed ingredients, at the claimed dosages, to the claimed patients, a holding of obviousness is clearly required.

Lastly, it is noted that applicant refers to a synergistic effect. However, applicant does not point to the evidence of record which demonstrates such synergy. Moreover, particularly with respect to the issue of obviousness, it is clearly improper for applicant to base their entire disclosure on the predictability of the IL-12-inducing properties of AHCC, then assert that it might not work when faced with prior art demonstrating its prior use in the same manner, using the same dosage. It is as if applicant is urging that an obviousness rejection is improper because their own disclosure is non-enabled, due to unpredictability. On the current record it is clear that the cited prior art suggests that all of the claimed ingredients would be suitably administered to a cancer patient. Therefore, the rejection must be maintained.

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No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone number for the

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organization where this application or proceeding is assigned is
(703) 872-9306.

Any inquiry of a general nature or relating to the status
of this application or proceeding should be directed to the
receptionist whose telephone number is 703-308-0196.



Francisco C Prats
Primary Examiner
Art Unit 1651

FCP